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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/639,453	08/15/2000	Arthur T. Sands	7705.0002-03	3310

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EXAMINER	
AKHAVAN, RAMIN	

ART UNIT	PAPER NUMBER
1636	

DATE MAILED: 03/10/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

Applicant 03/08/04 RA

Office Action Summary	Application No.	Applicant(s)	
	09/639,453	SANDS ET AL.	
	Examiner	Art Unit	
	Ramin (Ray) Akhavan	1636	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *06 January 2004*.

2a)☐ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *8 and 29-33* is/are pending in the application.

4a) Of the above claim(s) *8* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *29-33* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. § 119

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

Attachment(s)

1) ☒ Notice of References Cited (PTO-892)
2) ☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3) ☒ Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08) Paper No(s)/Mail Date *02/11/2004*.
4) ☐ Interview Summary (PTO-413) Paper No(s)/Mail Date. _____.
5) ☐ Notice of Informal Patent Application (PTO-152)
6) ☐ Other: _____.

DETAILED ACTION

A request for continued examination under 37 CFR 1.114, including the fee set forth in 37 CFR 1.17(e), was filed in this application after final rejection. Since this application is eligible for continued examination under 37 CFR 1.114, and the fee set forth in 37 CFR 1.17(e) has been timely paid, the finality of the previous Office action has been withdrawn pursuant to 37 CFR 1.114. Applicant's submission filed on 01/06/2004 has been entered. In that submission applicant introduced new claims 29-33. Claims 8 and 29-33 are pending in the instant application, with claim 8 being withdrawn from consideration as being directed to a nonelected invention.

Response to Amendment

Applicant's arguments in Remarks (filed 01/06/2004) with respect to rejections under double patenting, 35 U.S.C. §§ 102(a) and 102(e) have been considered but are moot in view of the new ground(s) of rejection. (See infra).

Claim Rejections - 35 USC § 112

The following is a quotation of the second paragraph of 35 U.S.C. 112:

> The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

1. **Claims 29-33 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.**

Base claim 29 is drawn to a library of cultured eukaryotic cells comprising at least two subpopulations of cells, wherein the first subpopulation have an integration vector mediating

splicing of a foreign exon internal to a cellular transcript and a second subpopulation having an integration vector mediating splicing of a foreign exon 5' to an exon of a cellular transcript. It is unclear how the latter subpopulation differs from the former, thus how there can be "at least two subpopulations." For example, both parts (a) and (b) are directed to the same outcome, thus there would only be one subpopulation. Put another way claim 29(a) is the equivalent of 29(b) and vice versa, because a vector mediating splicing of a foreign exon 5' to an cellular exon also mediates "splicing of a foreign exon internal to a cellular transcript". This ambiguity between separate parts of claim 29 confers indefiniteness with regard to the metes and bounds of the claim, as there is an internal conflict between the claim body and the claim preamble. Dependant claims are also rejected.

Claim Rejections - 35 USC § 102

(a) the invention was known or used by others in this country, or patented or described in a printed publication in this or a foreign country, before the invention thereof by the applicant for a patent.

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

2. Claims 29 is rejected under 35 U.S.C. 102(a) as being anticipated by Nussaume et al. (Mol. Gen. Genet., Nov. 1995; 249:91-101; hereinafter Nussaume).

The claims are drawn to a library of cultured eukaryotic cells, wherein a cell subpopulation have a vector integration mediated splicing of a foreign (i.e vector-borne) exon, 5' to a cellular transcript.

Nussaume teaches that this "gene trap" method allows cloning of genes (i.e. producing an index of genes or a library). (p. 91, col. 2, last ¶). Furthermore, the gene trap is used to transform eukaryotic cells (*Arabidopsis*) where splicing can be initiated from the splice donor site (Id.).

Therefore the fusion construct produced would necessarily have the foreign exon (i.e. reporter gene) fused to the 3' cellular transcript (i.e. the reporter is 5' to the cellular transcript). In short, Nussaume anticipates claim 29.

3. Claims 29-33 are rejected under 35 U.S.C. 102(b) as being anticipated by Yoshida et al. (Transgenic Research, July 1995; 4:277-87; hereinafter Yoshida).

The claims are drawn to a library of cells wherein a subpopulation of cultured eukaryotic cells have an integration mediating splicing of a foreign (i.e vector-borne) exon 5' to a cellular transcript. Furthermore, the cells can be mammalian, animal, rodent or mouse cells.

Yoshida teaches a "gene trapping" method in embryonic stem (ES) cells to identify a series of cell clones (i.e. library), wherein the cells have a gene trapping vector integrated nonspecifically (p. 278, col. 1, even in genes that are not being expressed. (e.g. Abstract, p. 278, col. 1, bottom ¶). When the gene trap integrates into a transcriptional unit, the normal expression pattern of the tagged gene can be followed by expression of the reporter, and the insertion creates a mutation as well.

More specifically, Yoshida teaches that a splicing donor signal produces a fusion construct (between integrant and trapped gene), which consists of a 3' end of the tagged gene. (Id.) In other words, the cells have an integrating vector that mediates splicing of a foreign exon internal to a cellular transcript, where the splicing of the foreign exon is 5' to a cellular exon. Yoshida teaches that the cells are mammalian, animal, rodent and mouse cells. (p. 278, col. 2, ¶ 4). Therefore Yoshida anticipates the rejected claims.

Double Patenting

The nonstatutory double patenting rejection is based on a judicially created doctrine grounded in public policy (a policy reflected in the statute) so as to prevent the unjustified or improper timewise extension of the "right to exclude" granted by a patent and to prevent possible harassment by multiple assignees. See *In re Goodman*, 11 F.3d 1046, 29 USPQ2d 2010 (Fed. Cir. 1993); *In re Longi*, 759 F.2d 887, 225 USPQ 645 (Fed. Cir. 1985); *In re Van Ornum*, 686 F.2d 937, 214 USPQ 761 (CCPA 1982); *In re Vogel*, 422 F.2d 438, 164 USPQ 619 (CCPA 1970);and, *In re Thorington,* 418 F.2d 528, 163 USPQ 644 (CCPA 1969).

A timely filed terminal disclaimer in compliance with 37 CFR 1.321(c) may be used to overcome an actual or provisional rejection based on a nonstatutory double patenting ground provided the conflicting application or patent is shown to be commonly owned with this application. See 37 CFR 1.130(b).

Effective January 1, 1994, a registered attorney or agent of record may sign a terminal disclaimer. A terminal disclaimer signed by the assignee must fully comply with 37 CFR 3.73(b).

4. Claims 29-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7 and 10 of U.S. Patent No. 6,136,566 ('566 patent).

Instant claims 29-33, as compared to reference claims 1-7 and 10, are related as genus claims to sub-genus or species claims. As such, the reference claims necessarily anticipate the instant claims.

Instant base claim 29 is drawn to a library of cultured eukaryotic cells where a subpopulation of cells have a vector mediated splicing of foreign exon 5' or internal to a cellular transcript. Meanwhile, the reference base claim 1 is drawn to a more particularized version drawn to substantially similar subject matter, where a collection of cultured eukaryotic cells have a first and second group of cells, where integrating vectors mediate splicing either through a splice acceptor or donor positioned 5' and 3' respectively to the foreign exon.

To summarize, the claims of the '566 patent anticipate and thus necessarily make obvious, the broader claims from the instant application.

In addition, if a patent resulting from instant claims were issued and transferred to an assignee different from the assignee for the '566 patent, then two different assignees would hold a patent to the subject matter of '566. Thus, improperly, there would be possible harassment by multiple assignees. Therefore, a patent to the genus (instant claims) would, necessarily, extend the right of the species or sub-genus (reference claims) should the genus issue as a patent after the species or sub-genus. The dependant claims in both instant application and the '566 patent are drawn to more particularized cells (e.g. mammalian, rodent).

5. Claims 29-33 are rejected under the judicially created doctrine of obviousness-type double patenting as being unpatentable over claims 1-7, 25-28 and 37 of U.S. Patent No. 6,207,371 ('371 patent).

The same analysis as in rejection No. 4 (supra) applies here. Again, the instant claims are a genus as compared to the sub-genus or species reference claims. Here, the reference base claim 1 is more particularized to a collection of eukaryotic cells with a first and second group of cells, having vector mediated splicing to produce fusion constructs of the foreign exon and trapped gene using splice acceptor and splice donor sites operatively linked 5' or 3' to the foreign exon. In addition reference claims 25-28 and 37 are drawn to cultured embryonic stem cells, also modified with the integration vectors of the invention. Therefore the reference claims anticipate the instant claims.

Conclusion

No claims are allowed.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ramin (Ray) Akhavan whose telephone number is 571-272-0766. The examiner can normally be reached on Monday- Friday from 8:00-4:30. If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Remy Yucel, Ph.D. can be reached on 571-272-0781. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.

Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see http://pair-direct.uspto.gov. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

GERRY LEFFERS
PRIMARY EXAMINER